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| SERIAL NUMBER | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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07/739,014 07/31/91 YAMAMOTO

| EXAMINER |
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18N1

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| ART UNIT | PAPER NUMBER |
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1813

DATE MAILED:

05/14/93

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 2-16-93 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1, 2, 4-8 and 10 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. ☒ Claims 3 and 9 have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 1, 2, 4-8 and 10 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).

12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received

☐ been filed in parent application, serial no. _____; filed on _____

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15. Applicant's cancellation of claims 3 and 9 in Paper No. 10 is acknowledged. Claims 1, 2, 4-8 and 10 are pending. Those sections of 35 U.S. Code not included in this office action can be found in the prior office action. All prior objections and rejections are withdrawn with the exception of those discussed below.

16. The prior provisional rejection of claims 1, 2, 4-8 and 10 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-6 and 8-11 of copending application Serial No. 07/726,061 (now pending as claims in the file wrapper continuation application Serial No. 07/995,304) is maintained.

17. The prior rejection of claims 1, 2, 4-8 and 10 under 35 U.S.C. 112, first paragraph, as the disclosure is not enabling for the entire scope of the claims as written, is maintained. The disclosure is enabling only for claims limited to a vaccine protective against FIV, wherein the immunogen is inactivated whole FIV or an inactivated cell line which expresses FIV antigens. The disclosure is not enabling for vaccines protective against viruses other than FIV, or for vaccines comprising FIV immunogens other than inactivated FIV-infected cell lines or inactivated, whole FIV (i.e. a vaccine comprising attenuated FIV, vaccines comprising individual FIV proteins or peptides). For example, it is unclear from the specification how one will purify or produce the myriad of FIV "immunogens" encompassed by the claims, and effectively use each FIV immunogen encompassed by the claims to protect against viral infection. Because Applicant has not provided a reasonable amount of guidance in the specification regarding how one will make and effectively use the broadly claimed vaccines and methods, it is maintained that undue experimentation would be required by one of ordinary skill in the art to practice the claimed invention.

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18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

19. Papers relating to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4227.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna L. Barnd whose telephone number is (703) 308-3908. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 180 receptionist whose telephone number is (703) 308-0196.

May 4, 1993
Donna L. Barnd, Ph.D.


CHRISTINE M. NUCKER
SUPERVISORY PATENT EXAMINER
GROUP 180